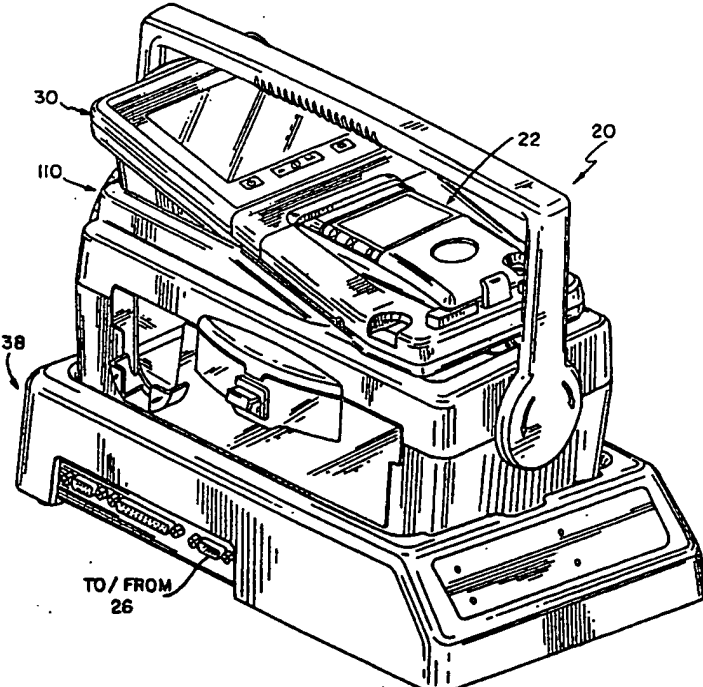




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : G06F 19/00	A1	(11) International Publication Number: WO 00/52626 (43) International Publication Date: 8 September 2000 (08.09.00)
(21) International Application Number: PCT/US00/05121 (22) International Filing Date: 29 February 2000 (29.02.00) (30) Priority Data: 60/122,285 1 March 1999 (01.03.99) US (71) Applicant: ROCHE DIAGNOSTICS CORPORATION [US/US]; 9115 Hague Road, Indianapolis, IN 46250 (US). (72) Inventors: KURTOCK, James, R.; 10787 Red Pine Drive, Fishers, IN 46038 (US). RICHARDS, Sandy, Mark; 319 Main Street, Pershing, IN 47370 (US). (74) Agent: CONARD, Richard, D.; Barnes & Thornburg, 11 South Meridian Street, Indianapolis, IN 46204 (US).		(81) Designated States: AU, CA, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.
(54) Title: HEALTH CARE DATA MANAGEMENT SYSTEM (57) Abstract <p>A healthcare data management system (20) for use with an instrument (22) for determining the concentration of a medically significant component of a body fluid. The instrument (22) includes a first port (24). The system includes a cradle (30) for receiving the instrument (22). The cradle (30) includes a second port (32) for coupling to the first port (24) to download data from the instrument (22) to the cradle (30). The system (20) further includes a base (38) having a third port (40). The cradle (30) includes a fourth port (42) for coupling to the third port (40) to permit downloading to the base (38) of data collected from the instrument (22) by the cradle (30). The system (20) further includes an accessory box (110) including a fifth port (166). Engagement of the cradle (30) with the accessory box (110) couples the fourth (42) and fifth (166) ports. Engagement of the accessory box (110) with the base (38) couples (166, 168, 163, 170, 172) the third (40) and fifth ports (166).</p> 		

BEST AVAILABLE COPY

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## HEALTH CARE DATA MANAGEMENT SYSTEM

Cross-Reference To Related Applications

Reference is hereby made to U.S. design patent application 29/101,237,  
5 titled CRADLE FOR INSTRUMENT filed March 1, 1999, and assigned to the same  
assignee, U.S. design patent application 29/101,236, titled ACCESSORY BOX FOR  
CRADLE FOR INSTRUMENT filed March 1, 1999, and assigned to the same  
assignee, and U.S. design patent application 29/101,274, titled BASE FOR CRADLE  
10 FOR INSTRUMENT OR FOR ACCESSORY BOX FOR CRADLE FOR  
INSTRUMENT filed March 1, 1999, and assigned to the same assignee, all of which  
are hereby incorporated herein by reference.

Field of the Invention

This invention relates to hospital and health care facility data  
15 management. It is disclosed in the context of a blood glucose data management  
system, but is believed to be useful in other applications as well.

Background of the Invention

Various systems for the acquisition and management of health care data  
20 are known. The systems described in the following listed U.S. patents are illustrative  
only, and are by no means intended to be an exhaustive listing of the known types of  
systems: 4,871,258; 5,011,290; 5,160,980; 5,232,668; 5,246,858; 5,284,770;  
5,366,609; 5,379,214; 5,371,687; 5,508,171; 5,594,906; 5,522,255; 5,686,659;  
5,710,622; 5,789,664; 5,792,944; 5,832,921; and 5,841,023. The disclosures of these  
25 patents are hereby incorporated herein by reference.

Disclosure of the Invention

Illustratively, according to the invention, a data acquisition and  
management system is provided for downloading health care data, for example,  
30 glucose concentrations in bodily fluids such as blood, determined by, and stored in,  
instruments such as, for example, Roche Diagnostics Corporation's Accucheck®  
Advantage™ and Accucheck® Complete™ hand-held blood glucose monitoring

instruments. Such an instrument typically includes a first input/output (I/O) port for the entry of, for example, instructions and operating parameters into the instrument, and the downloading of data from the instrument to a host, such as, for example, a system of the type described in the above-identified U.S. Patents Nos. 5,371,687 and  
5 5,594,906. The system keeps track of the identities of the instruments from which it receives data. In this way, the system can, for example, identify the data with a particular patient to whom a particular instrument is assigned.

According to the one aspect of the invention, a healthcare data management system is provided for use with an instrument for determining the  
10 concentration of a medically significant component of a body fluid. The instrument includes a first port. The system includes a cradle for receiving the instrument. The cradle includes a second port for coupling to the first port to download data from the instrument to the cradle.

Illustratively according to this aspect of the invention, the cradle further  
15 includes means for the entry of data by an operator. Illustrative data entry means include touch screens and/or key pads for the manual entry of data.

Further illustratively according to this aspect of the invention, the system includes a base. The base includes a third port and the cradle includes a fourth port. Coupling of the third and fourth ports permits downloading to the base of data  
20 collected from the instrument by the cradle.

Additionally illustratively according to this aspect of the invention, coupling of the third and fourth ports includes providing complementary surfaces on the cradle and base. Engagement of the complementary surfaces of the cradle and base couples the third and fourth ports.

25 Illustratively according to this aspect of the invention, the cradle includes at least one rechargeable battery for powering circuitry in the cradle. The base includes a power supply. Coupling of the third and fourth ports permits charging of the battery from the power supply.

Further illustratively according to this aspect of the invention, the base  
30 includes a fifth port for coupling to a port on a computer to permit transmission of data from the base to the computer.

Additionally illustratively according to this aspect of the invention, the system includes a computer for storing and/or analyzing and/or generating reports based upon the data. The base includes a fifth port for coupling to a sixth port on the computer.

5 Illustratively according to this aspect of the invention, the system includes a bar code reader. The system is capable of reading bar code from patient identification devices to identify data which is entered into the system with a particular patient.

10 Additionally or alternatively illustratively according to this aspect of the invention, the system is capable of reading bar code from operator identification devices to identify data which is entered into the system with a particular operator.

Illustratively according to this aspect of the invention, the bar code reader is incorporated into the cradle.

15 Further illustratively according to this aspect of the invention, the system includes an accessory box including a seventh port. Engagement of the cradle with the accessory box couples the fourth and seventh ports.

20 Additionally illustratively according to this aspect of the invention, coupling of the fourth and seventh ports includes providing complementary surfaces on the accessory box and cradle. Engagement of the complementary surfaces of the accessory box and cradle couples the fourth and seventh ports.

Illustratively according to this aspect of the invention, coupling of the third and fourth ports includes providing complementary surfaces on the accessory box and base. Engagement of the complementary surfaces of the accessory box and base couples the third and fourth ports through the seventh port.

25 Further illustratively according to this aspect of the invention, the accessory box includes a housing and a carrying handle pivotally coupled to the housing.

30 Additionally illustratively according to this aspect of the invention, the carrying handle has two ends. One of the ends includes a number of yieldable locking positions for the handle with respect to the housing.

Further illustratively according to this aspect of the invention, the handle includes a locking position of the handle with respect to the housing.

Illustratively according to this aspect of the invention, at least one of the handle and the cradle includes a feature for engagement with the other of the cradle and the handle when the cradle engages the accessory box and the handle is in the non-yieldable locking position.

5                   Further illustratively according to this aspect of the invention, the accessory box includes a drawer accessible from two opposite sides of the accessory box. The drawer includes a stop for reducing the likelihood of accidental disengagement of the drawer from the accessory box when the accessory box is withdrawn from either of said two opposite sides.

10                  Additionally illustratively according to this aspect of the invention, the drawer includes latches to reduce the likelihood of inadvertent opening of the drawer.

                  According to another aspect of the invention, a healthcare data management system for use with an instrument for determining the concentration of a medically significant component of a body fluid includes a cradle for receiving the  
15                  instrument and an accessory box for receiving the cradle. The accessory box includes a housing and a carrying handle pivotally coupled to the housing. The carrying handle has two ends. One of the ends includes a number of yieldable locking positions for the handle with respect to the housing.

                  Illustratively according to this aspect of the invention, the handle  
20                  further includes a non-yieldable locking position with respect to the housing.

                  Further illustratively according to this aspect of the invention, the handle includes a feature for engagement with the cradle when the cradle engages the accessory box and the handle is in the non-yieldable locking position.

                  Additionally illustratively according to this aspect of the invention, the  
25                  accessory box includes a drawer accessible from two opposite sides of the accessory box. The drawer includes a stop for reducing the likelihood of accidental disengagement of the drawer from the accessory box when the accessory box is withdrawn from either of the opposite sides.

                  Illustratively according to this aspect of the invention, the accessory  
30                  box includes a drawer accessible from two opposite sides of the accessory box. The drawer includes latches to reduce the likelihood of inadvertent opening of the drawer.

Further illustratively according to this aspect of the invention, one of the ends includes a button which is yieldably urged into engagement with one of a number of depressions which define the yieldable locking positions of the handle.

Additionally illustratively according to this aspect of the invention, said  
5 one of the ends further includes an opening which defines a non-yieldable locking position of the handle.

Illustratively according to this aspect of the invention, the bottoms of the depressions are formed to include ramps to permit force on the handle to move the handle among the yieldable locking positions defined by the depressions.

10 Further illustratively according to this aspect of the invention, the opening includes a sidewall which defines the non-yieldable locking position. The sidewall is configured to permit locking of the handle in the non-yieldable locking position.

Additionally illustratively according to this aspect of the invention, the  
15 opening permits access to the button to permit movement of the handle from the non-yieldable locking position.

Illustratively according to this aspect of the invention, at least one of the handle and the cradle includes a feature for engagement with the other of the cradle and the handle when the cradle engages the accessory box and the handle is in the non-  
20 yieldable locking position.

#### Brief Description of the Drawings

The invention may best be understood by referring to the following detailed description and accompanying drawings which illustrate the invention. In the  
25 drawings:

Fig. 1 illustrates a perspective view of a component of a system constructed according to the invention;

Fig. 2 illustrates a fragmentary exploded perspective view of the component illustrated in Fig. 1;

30 Fig. 3 illustrates a side elevational view of a detail of the component illustrated in Figs. 1-2, taken generally along section lines 3-3 of Fig. 2;

Fig. 4 illustrates a perspective view of a component of a system constructed according to the invention with an instrument for testing for glucose concentration inserted into it;

Fig. 5 illustrates a perspective view of a component of a system  
5 constructed according to the invention;

Fig. 6 illustrates a fragmentary exploded perspective view of the component illustrated in Fig. 5;

Fig. 7 illustrates an enlarged, partly sectional side elevational view of a detail of the components illustrated in Figs. 1-6;

Fig. 8 illustrates an enlarged top plan view of a detail of the component  
10 illustrated in Figs. 5-6;

Fig. 9 illustrates a side elevational view of a detail of the component illustrated in Figs. 5-6, taken generally along section lines 9-9 of Fig. 5;

Fig. 10 illustrates a sectional view of the detail illustrated in Fig. 9,  
15 taken generally along section lines 10-10 of Fig. 9;

Fig. 11 illustrates a sectional view of the detail illustrated in Figs. 9-10, taken generally along section lines 11-11 of Fig. 10;

Fig. 12 illustrates a perspective view of a component of a system constructed according to the invention; and,

20 Figs. 13 and 14 illustrate partly fragmentary perspective views of two systems according to the present invention.

#### Detailed Description of an Illustrative Embodiment

Turning now particularly to Figs. 1-2, 4, 13 and 14, a data acquisition  
25 and management system 20 is provided for downloading health care data, for example, glucose concentrations in bodily fluids such as blood, determined by, and stored in, instruments 22 such as, for example, Accucheck® Advantage™ and Accucheck® Complete™ hand-held blood glucose monitoring instruments. Such an instrument 22 typically includes a first, illustratively infrared (IR), input/output (I/O) port 24 for the  
30 entry of, for example, instructions and operating parameters into the instrument 22, and the downloading of data from the instrument 22 to a host computer 26 (Fig. 12), such as, for example, a hospital data management system of the type described in the



above-identified U.S. Patents 5,371,687 and 5,594,906, or the printing of reports directly from the cradle 30 via a printer port on the base 38. The system 20 keeps track of the identities of the patients and/or operators from whom it receives data. In this way, the system 20 can, for example, identify the data with a particular patient  
5 and/or with a particular operator who is taking readings/entering data into the system 20.

The system 20 includes such an instrument 22 and a cradle 30 for receiving the instrument 22. The cradle 30 may include a second, illustratively, IR, I/O port 32 for coupling to the first port 24 provided on the instrument 22 to download  
10 data from the instrument 22 to the cradle 30. The cradle 30 also includes a touch screen 33 and liquid crystal display (LCD) 34, key pad, or the like for the manual entry of data by an operator. The system 20 further includes a base 38 (Fig. 12). The base 38 includes a third port 40 for coupling to a fourth port 42 on the cradle 30. Coupling of the third and fourth ports 40, 42 permits downloading of data from the cradle 30  
15 through the base 38. Coupling of the third and fourth ports 40, 42 permits charging of batteries 44 used to power circuitry 45 in the cradle 30 from a power supply in the base 38. The use of rechargeable batteries 44 reduces the requirement to change batteries. The illustrated base 38 further includes a fifth port 46 for coupling to a port 48 on computer 26 to permit the downloading of data through the base 38 to the  
20 computer 26 for storage, analysis and report generation, or for coupling directly to a printer (not shown) for the printing of reports directly from cradle 30. A port 49 in the base 38 permits the base 38 to be coupled directly to a printer (not shown).

The system illustratively includes a bar code reader 52 (illustrated in phantom in Fig. 2). The bar code reader 52 has a number of different uses. For  
25 example, each patient may be provided with a bar coded patient identification tag/card and/or each operator may be provided with a bar coded operator identification tag/card. The system 20 reads the bar code labels to identify data which is downloaded into the system 20 with a particular patient and/or operator. Readings are thereby capable of being associated with a particular patient and/or with a particular  
30 operator. Illustratively, the bar code reader 52 may be factory installed into the cradle 30, or may be a field-installed addition to the cradle 30. The bar code reader 52 can include, for example, a Metrologic model MH4110 or MS4120 scan engine.

The cradle 30 includes a housing top portion 60 and a housing bottom portion 62. Housing bottom portion 62 is divided into a forward portion 64 and a separate rearward portion 66. The bar code reader 52 is housed in the rearward portion 66 and is exposed through a scan window 68 provided in the bottom of portion 66 to bar code labels 50 to be read. The batteries 44 are also housed in housing portion 66. Housing portions 62, 64, 66 illustratively are molded from filled or unfilled resins, such as, for example, an ABS-polycarbonate composite. The forward portion 64 is provided with a desired number, five in the illustrated embodiment, of probe spring contact openings 68 into which spring contact probes 70 are press fitted. One of these probes 70 is illustrated in greater detail in Fig. 7. Probes 70 illustratively include gold plated nickel silver barrels 72, gold plated hard beryllium copper plungers 74 and gold plated stainless steel springs 76. A molded-in retainer is provided at the front of bottom portion 64 to receive a front hook 78. Front hook 78 is illustrated in enlarged side elevation in Fig. 3. Its purpose will be discussed hereinafter. The rear top region of bottom portion 64 is provided with a passageway for accommodating a stylus 80 which can be used to enter data into touch screen 33 of the cradle 30.

Probes 70 are electrically connected to appropriate terminals of the circuit 45 which is provided on a circuit board 84. Circuit board 84 is mounted in the cradle 30 during the assembly of portions 62, 64. Touch screen 33 is coupled by a multi-conductor ribbon cable and complementary plug and socket to circuit board 84, and is driven by driver circuitry in circuit 45. An LCD 34/backlight 88 assembly is coupled by a multi-conductor ribbon cable and complementary plug and socket to circuit board 84, and is driven by driver circuitry in circuit 45. A threaded fastener 90 and molded ears 92 cooperating with slots 94 in housing bottom portion 64 attach housing bottom rear portion 66, with reader 52 housed therein, to housing bottom portion 64. Threaded fasteners 96 secure housing bottom portion 64 to housing top portion 62.

Housing top portion 62 is provided with a slot 98 adjacent its front surface. Front hook 78 protrudes through slot 98 above the top surface 100 of housing top portion 62. Housing top portion 62 is further provided with an opening through which LCD 34 is visible and accessible. Housing top portion 62 is also

provided with a recess 102 having an overall configuration generally complementary in shape to the shape(s) of the instrument(s) 22 with which cradle 30 is designed to be used. As such, this recess 102 may be a composite of a number of different shapes, to accommodate a number of different types, styles and/or models of instruments 22. A  
5     retainer 104 snaps onto housing top portion 62 at the rearward extent of recess 102. Retainer 104 helps to retain instrument 22 in recess 102 by holding it against front hook 78. Instruments 22 are inserted into recess 102 and urged against the back wall 106 thereof, and snapped into place and held in place with the cooperation of front hook 78 and retainer 104.

10             Turning now to Figs. 5-11, an accessory box 110 useful in transporting cradle 30 from place to place will be described in greater detail. Accessory box 110 includes a housing bottom portion 112 and a housing top portion 116, both of which illustratively are injection molded or otherwise formed from suitable filled or unfilled resins, and a ceiling plate 114, which illustratively is constructed from stamped metal,  
15     all held together, for example, by threaded fasteners 118. The rear region of housing bottom portion 112 includes a rear wall 120 having two upwardly opening semicircular cutouts 122, 124 formed therein. Cutout 122 is generally centered in the span of wall 120. Cutout 124 is offset to one side. A partial wall 126 extends upward from the floor of housing bottom portion 112 forward of wall 120. Partial wall 126 has a  
20     cutout 128 formed in the upper extent thereof to receive the shank 130 of a locking button 132. A coil compression spring 136 is captured on shank 130 between partial wall 126 and a collar 138 formed on button 132 to urge button 132 out of rear wall 120. Collar 138 also captures button 132 in rear wall 120.

           The forward region of housing bottom portion 112 includes a forward  
25     wall 140 having an upwardly opening semicircular cutout 142 formed therein. Cutout 142 is generally centered in the span of wall 140. Housing top portion 116 includes a rear wall 144 having two downwardly opening semicircular cutouts 122, 124 complementary to cutouts 122, 124 in wall 120 formed therein, and a forward wall 146 having a downwardly opening semicircular cutout 142 complementary to cutout 142 in  
30     wall 140 formed therein. A carrying handle 150 includes a handgrip 152 and two ends 154, 156 for positioning at the back and front, respectively, of accessory box 110. Each end 154, 156 includes a pivot post 158 for engagement in a respective hole

-10-

formed by a respective pair of cutouts 122, 122 and 142, 142. Pivot posts 158 are provided with retaining projections which prevent the posts 158 from disengaging from accessory box 110. One, 154, of the ends includes a circumferentially extending channel 160 for accommodating button 132. The bottom of channel 160 includes a number, illustratively four, of depressions 162 which define locking positions for handle 150, and an opening 164 which defines a central locking position of handle 150. The contours of the bottoms of depressions 162 are best illustrated in Fig. 11. As can be appreciated from Fig. 11, the contours of the bottoms of depressions 162 are smoothly curved to permit force on the handle 150 to move the handle among the positions defined by depressions 162 without damaging the handle 150 or the button 132. The depressions 162 are generally somewhat egg-shaped or elliptical in plan view to enhance this releasing characteristic of the handle 150 in these positions. The sidewalls of the central opening 164 are generally straight to permit more secure locking of handle 150 in the upright position. Opening 164 permits access to button 132 when handle 150 is in the upright position to release button 132 and permit movement of handle 150 from the upright position. When handle 150 is in the upright position and a cradle 30 is engaged in the recess 165 provided therefor on the top of accessory box 110, the cradle 30 is locked into the recess 165 by the engagement of stops 167 and 169 provided on the accessory box 110 and handle 150, respectively. The handle 150 illustratively can be made by gas assisted injection molding to make the handle 150 more robust and capable of withstanding shock, for example, during drop testing.

Probes 70 of cradle 30 make electrical contact with corresponding terminals 166 provided and positioned for this purpose on housing top portion 116 when cradle 30 is positioned in housing top portion 116. A ribbon cable 163 includes plugs 168 and 170 for making electrical contact to terminals 166 and another set of terminals 172 in the housing bottom portion 112. Terminals 172 include probes 174 of the same general configuration and mounting as probes 70 for a purpose which will be described later. Housing 110 also includes a drawer 176 which can be withdrawn from either side of housing 110. Stops 178 provided in the bottom wall 180 of housing bottom portion 112 prevent the drawer 176 from being accidentally disengaged from housing 110, regardless of from which side of housing 110 drawer 176 is withdrawn.

Drawer 176 also includes spring 182-urged latches 184 which reside in wells 186 provided for latches 184 in both handles 188 of drawer 176. These latches 184 cooperate with stops 190 provided on housing top portion 116 to prevent the drawer 176 from accidentally coming open, for example, while accessory box 110 is being transported from station (for example, patient, nurses' station or the like) to station. Housing 110 components illustratively are also molded from filled or unfilled resins, such as, for example, an ABS-polycarbonate composite. Drawer 176 illustratively may be formed from a transparent or semi-transparent material such as, for example, polycarbonate.

As previously noted, the system 20 further includes base 38. Base 38 includes a third port 40 for coupling to a complementarily configured fourth port 42 on the cradle 30. Coupling of the third and fourth ports 40, 42 is achieved directly by placement of the cradle 30 directly on base 38, in which case probes 70 contact respective terminals 192 provided and positioned for this purpose on the top surface 194 of base 38. This permits downloading of data collected from instruments 22 by the cradle 30 through the base 38. Coupling of the third and fourth ports 40, 42 can also be achieved through the accessory box 110 when cradle 30 is positioned on an accessory box 110. In this case, the electrical connection is through probes 70, terminals 166, plug 168, ribbon cable 163, plug 170, terminals 172 and probes 174 to respective terminals 192 in base 38. The recess 195 in the top surface 194 of base 38 is configured to accept either cradle 30 or accessory box 110. Again, coupling of the third and fourth ports 40, 42 permits charging of batteries 44 used to power circuitry 45 in the cradle 30 through the base 38. The use of rechargeable batteries 44 reduces the requirement to change batteries. The illustrated base 38 further includes a fifth port 46 for coupling to a port 48 on computer 26 to permit the downloading of data through the base 38 to the computer 26 for storage, analysis and report generation. The bottom portion of base 38 illustratively is constructed from stamped metal and the top portion of base 38 illustratively is molded from filled or unfilled resins, such as, for example, an ABS-polycarbonate composite.

The illustrated system 20 is thus modular. The health care worker is afforded the flexibility to decide how much of the system 20 to transport to any given patient care site. For example, the worker may elect in certain instances to take only

the instrument 22 itself, with entry of data and patient identification being left to be performed, for example, in part by entry through touch screen 33 or key pad, at some site remote from the patient's location, for example, at a nurses' station on a ward in a hospital. Or, for example, the worker may elect to take an instrument 22 and the  
5 cradle 30 to a patient care site, or use the cradle 30 with an instrument 22 already at a patient care site. Optionally, the worker may elect to take an instrument 22, cradle 30, and an accessory box 110 to a patient care site.

CLAIMS:

1. A healthcare data management system for use with an  
5 instrument for determining the concentration of a medically significant component of a body fluid, the instrument including a first port, the system including a cradle for receiving the instrument, the cradle including a second port for coupling to the first port to download data from the instrument to the cradle.
2. The apparatus of claim 1 wherein the cradle further includes  
10 means for the entry of data by an operator.
3. The apparatus of claim 2 wherein the data entry means includes a touch screen for the manual entry of data.
4. The apparatus of claim 2 wherein the data entry means includes a key pad for the manual entry of data.
5. The apparatus of claim 1 further including a base, the base  
15 including a third port and the cradle including a fourth port, coupling of the third and fourth ports permitting downloading to the base of data collected from the instrument by the cradle.
6. The apparatus of claim 5 wherein coupling of the third and  
20 fourth ports includes providing complementary surfaces on the cradle and base, engagement of the complementary surfaces of the cradle and base coupling the third and fourth ports.
7. The apparatus of claim 5 wherein the cradle includes at least one rechargeable battery for powering circuitry in the cradle, the base including a  
25 power supply, coupling of the third and fourth ports permitting charging of the battery from the power supply.
8. The apparatus of claim 5 wherein the base includes a fifth port for coupling to a port on a computer to permit transmission of data from the base to the computer.
9. The apparatus of claim 5 and further including a computer for at  
30 least one of storing the data, analyzing the data, and generating reports based upon the data, the base including a fifth port for coupling to a sixth port on the computer.

10. The apparatus of claim 1 further including a bar code reader and patient identification devices, the system being capable of reading bar code from the patient identification devices to identify data which is entered into the system with a particular patient.

5 11. The apparatus of claim 10 wherein the bar code reader is incorporated into the cradle.

12. The apparatus of claim 1 further including a bar code reader and operator identification devices, the system being capable of reading bar code from the operator identification devices to identify data which is entered into the system with a particular operator.

13. The apparatus of claim 12 wherein the bar code reader is incorporated into the cradle.

14. The apparatus of claim 1 further including an accessory box including a third port, the cradle including a fourth port, engagement of the cradle with the accessory box coupling the third and fourth ports.

15. The apparatus of claim 14 wherein coupling of the third and fourth ports includes providing complementary surfaces on the accessory box and cradle, engagement of the complementary surfaces of the accessory box and cradle coupling the third and fourth ports.

20 16. The apparatus of claim 14 further including a base, the base including a fifth port, engagement of the accessory box with the base coupling the fifth port and the third port through the accessory box to permit downloading to the base of data collected from the instrument by the cradle.

25 17. The apparatus of claim 16 wherein coupling of the third and fifth ports includes providing complementary surfaces on the accessory box and base, engagement of the complementary surfaces of the accessory box and base being designed to achieve coupling of the third and fifth ports.

30 18. The apparatus of claim 16 wherein the base includes a sixth port for coupling to a port on a computer to permit the downloading of data from the base to the computer.

19. The apparatus of claim 16 and further including a computer for at least one of storing the data, analyzing the data, and generating reports based upon



the data, the base including a sixth port for coupling to a seventh port on the computer.

20. The apparatus of claim 14 wherein the accessory box further includes a housing and a carrying handle pivotally coupled to the housing.

5 21. The apparatus of claim 20 wherein the carrying handle has two ends, one of the ends including a number of yieldable locking positions for the handle with respect to the housing.

22. The apparatus of claim 21 further including a non-yieldable locking position of the handle with respect to the housing.

10 23. The apparatus of claim 22 wherein at least one of the handle and the cradle includes a feature for engagement with the other of the cradle and the handle when the cradle engages the accessory box and the handle is in the non-yieldable locking position.

24. The apparatus of claim 14 wherein the accessory box includes a  
15 drawer accessible from two opposite sides of the accessory box, the drawer including a stop for reducing the likelihood of accidental disengagement of the drawer from the accessory box when the accessory box is withdrawn from either of said two opposite sides.

25. The apparatus of claim 14 wherein the accessory box includes a  
20 drawer accessible from two opposite sides of the accessory box, the drawer including latches to reduce the likelihood of inadvertent opening of the drawer.

26. A healthcare data management system for use with an instrument for determining the concentration of a medically significant component of a body fluid, the system including a cradle for receiving the instrument, and an accessory  
25 box for receiving the cradle, the accessory box including a housing and a carrying handle pivotally coupled to the housing, the carrying handle having two ends, one of the ends including a number of yieldable locking positions for the handle with respect to the housing.

27. The apparatus of claim 26 further including a non-yieldable  
30 locking position of the handle with respect to the housing.

28. The apparatus of claim 27 wherein the handle includes a feature for engagement with the cradle when the cradle engages the accessory box and the handle is in the non-yieldable locking position.

29. The apparatus of claim 26 wherein the accessory box includes a  
5 drawer accessible from two opposite sides of the accessory box, the drawer including a stop for reducing the likelihood of accidental disengagement of the drawer from the accessory box when the accessory box is withdrawn from either of said two opposite sides.

30. The apparatus of claim 26 wherein the accessory box includes a  
10 drawer accessible from two opposite sides of the accessory box, the drawer including latches to reduce the likelihood of inadvertent opening of the drawer.

31. The apparatus of claim 26 wherein one of the ends includes a button which is yieldably urged into engagement with one of a number of depressions which define the yieldable locking positions of the handle.

15 32. The apparatus of claim 31 wherein said one of the ends further includes an opening which defines a non-yieldable locking position of the handle.

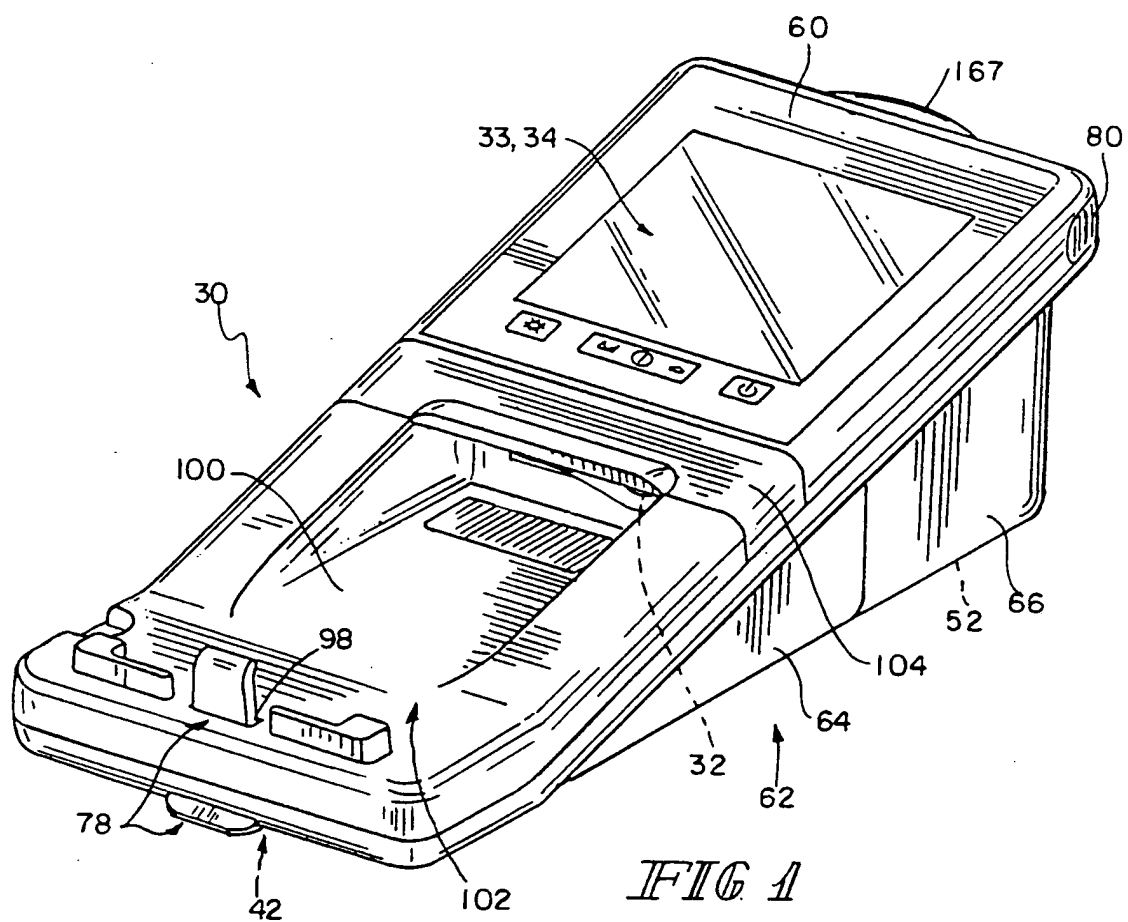
33. The apparatus of claim 31 wherein the bottoms of the depressions are formed to include ramps to permit force on the handle to move the handle among the yieldable locking positions defined by the depressions.

20 34. The apparatus of claim 32 wherein the opening includes a sidewall which defines the non-yieldable locking position, the sidewall being configured to permit locking of the handle in the non-yieldable locking position.

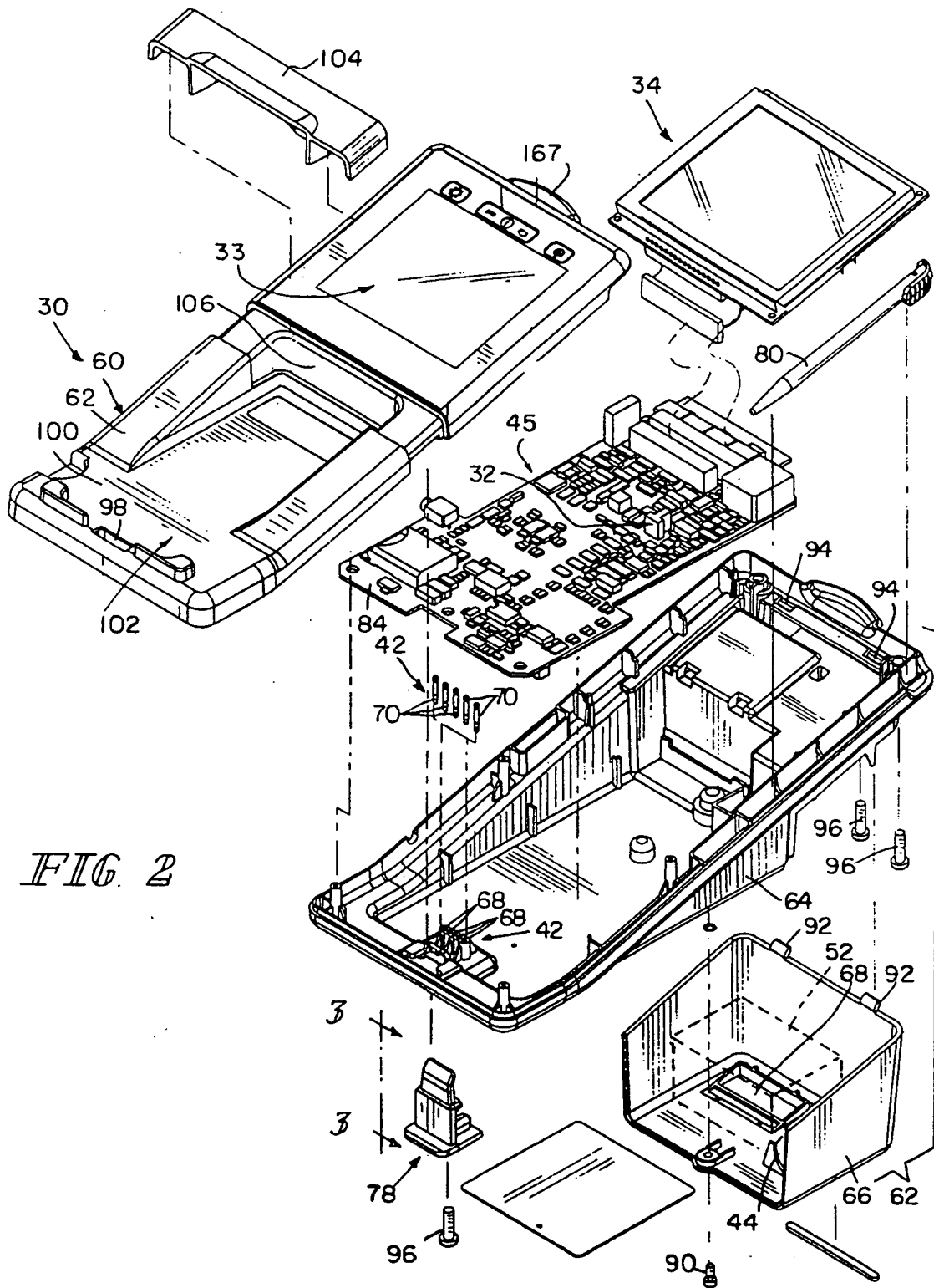
35. The apparatus of claim 34 wherein the opening permits access to the button to permit movement of the handle from the non-yieldable locking  
25 position.

36. The apparatus of claim 26 wherein at least one of the handle and the cradle includes a feature for engagement with the other of the cradle and the handle when the cradle engages the accessory box and the handle is in the non-yieldable locking position.

///



2/11



3/11

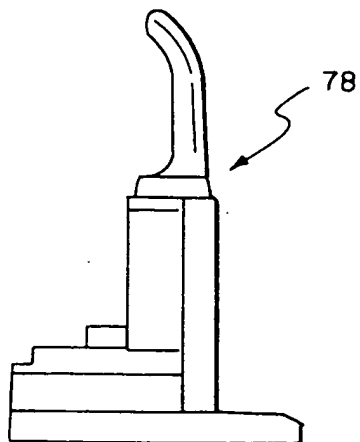


FIG 3

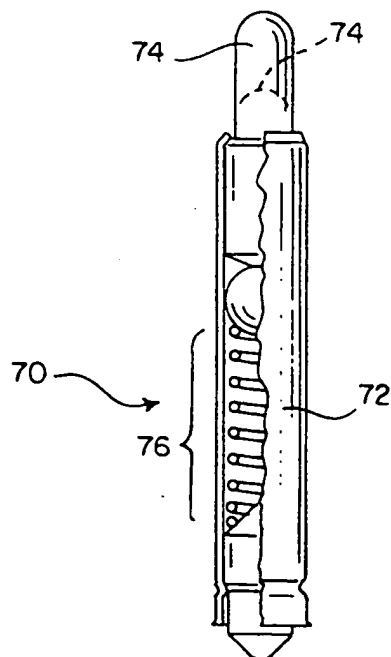


FIG 7

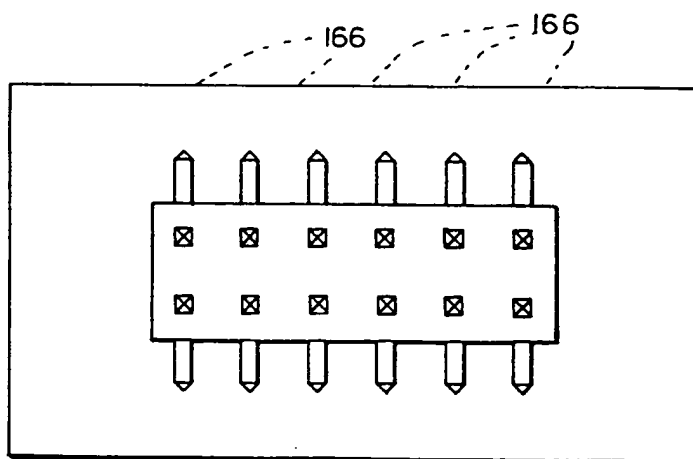


FIG 8



5/11

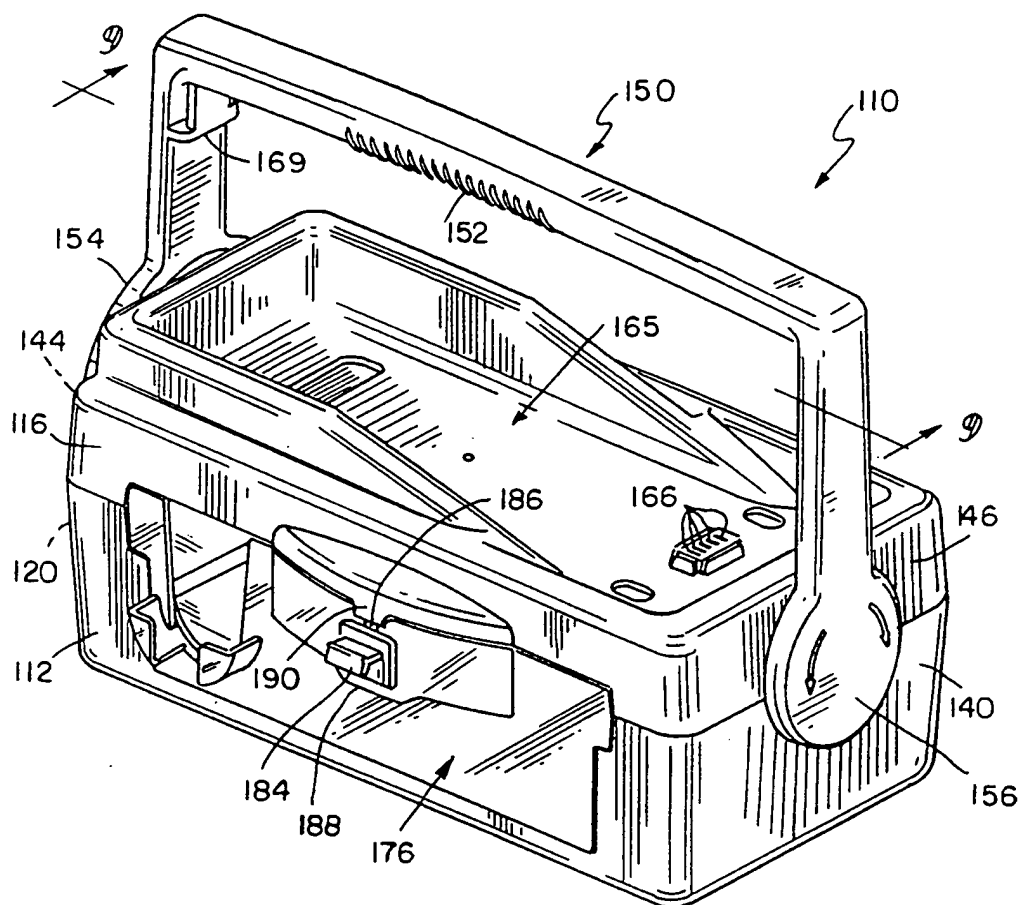
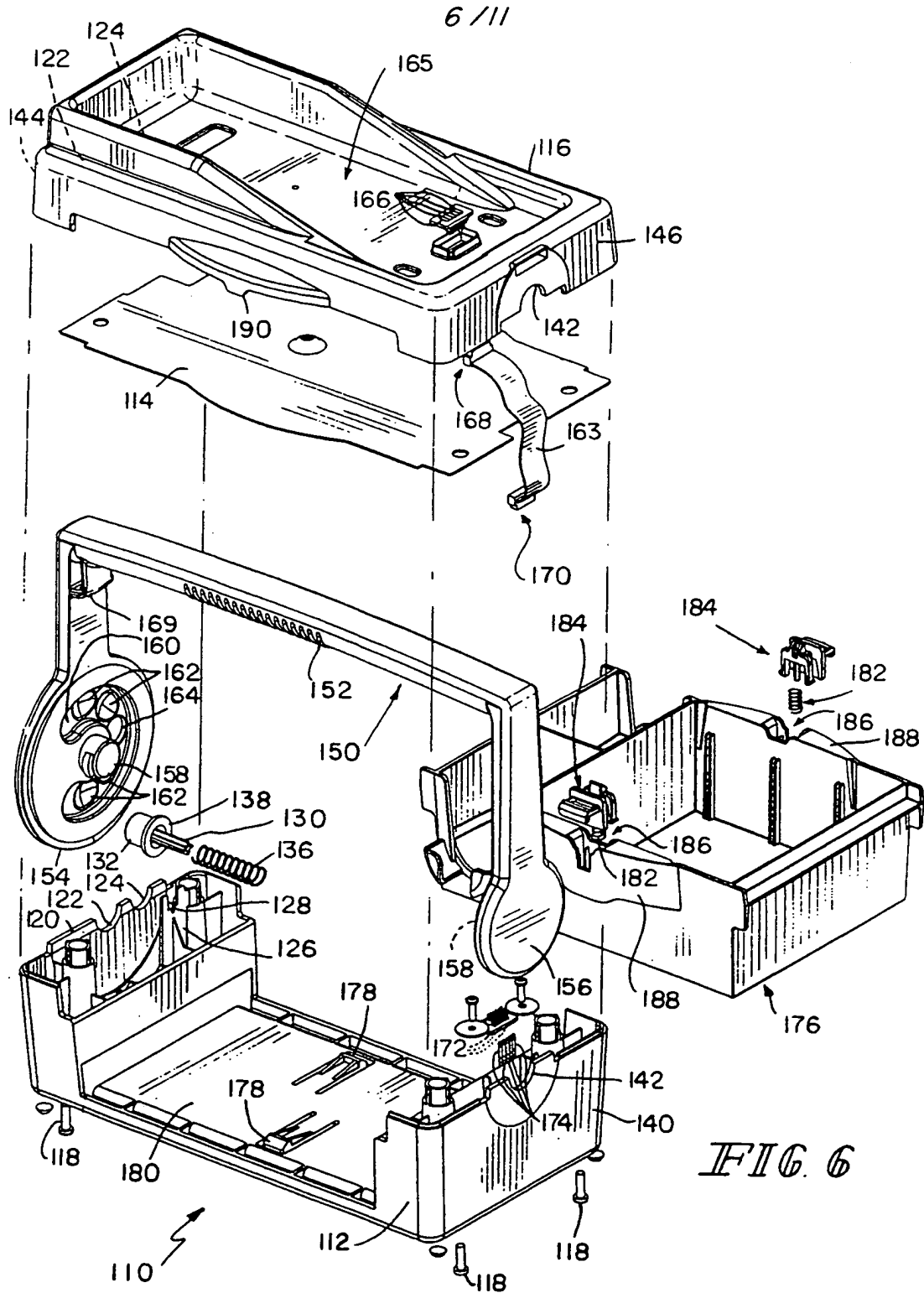
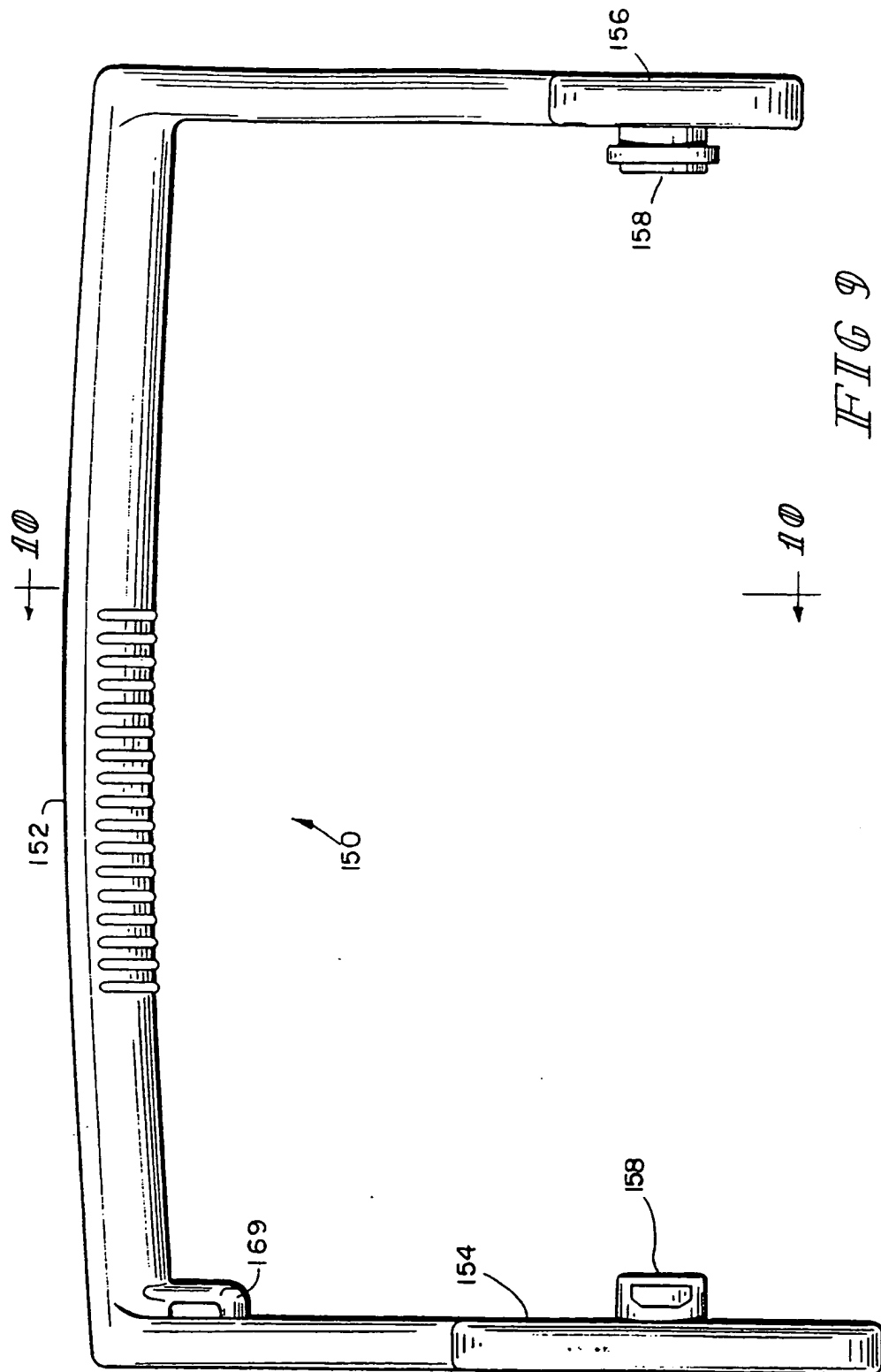


FIG 5

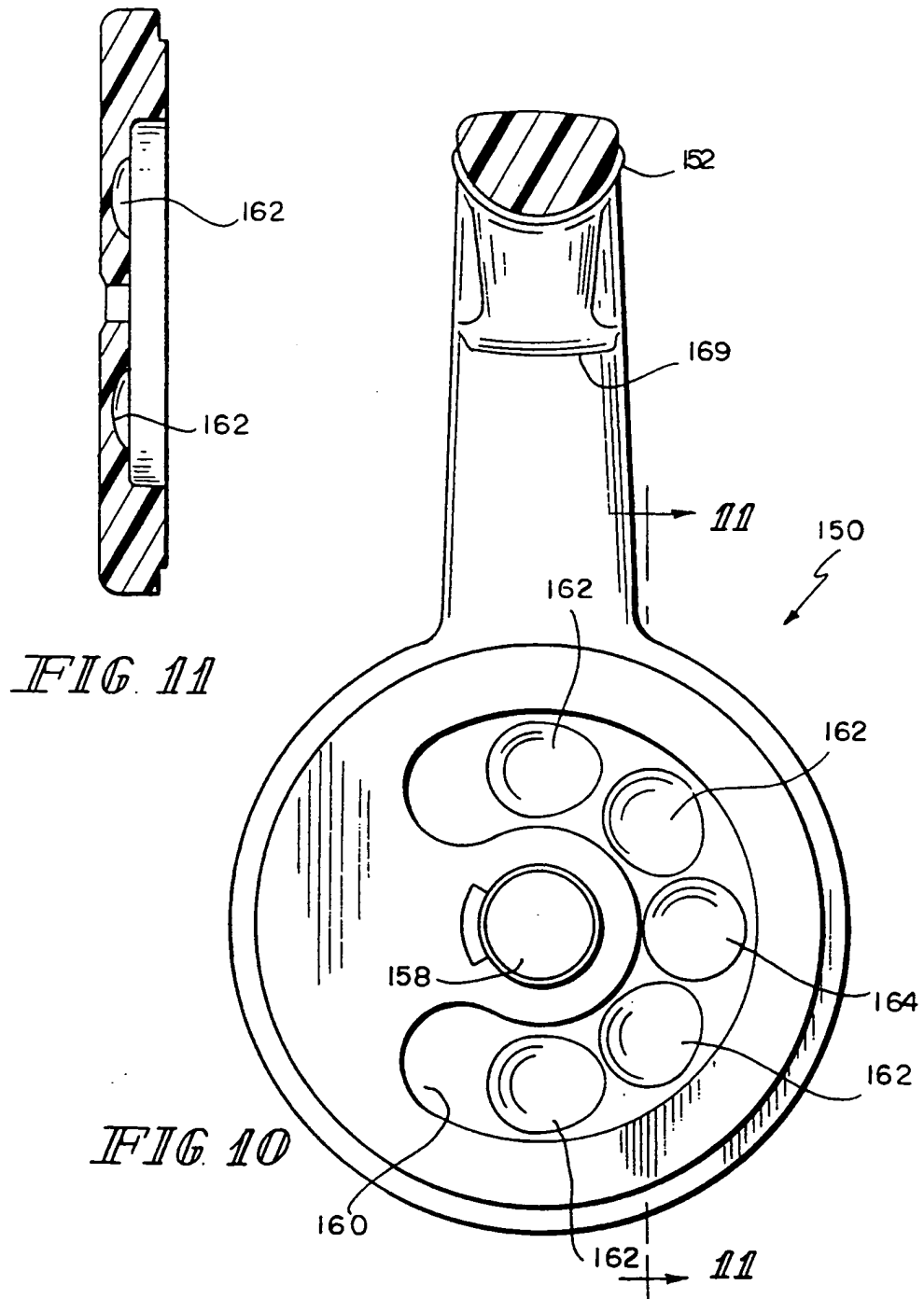




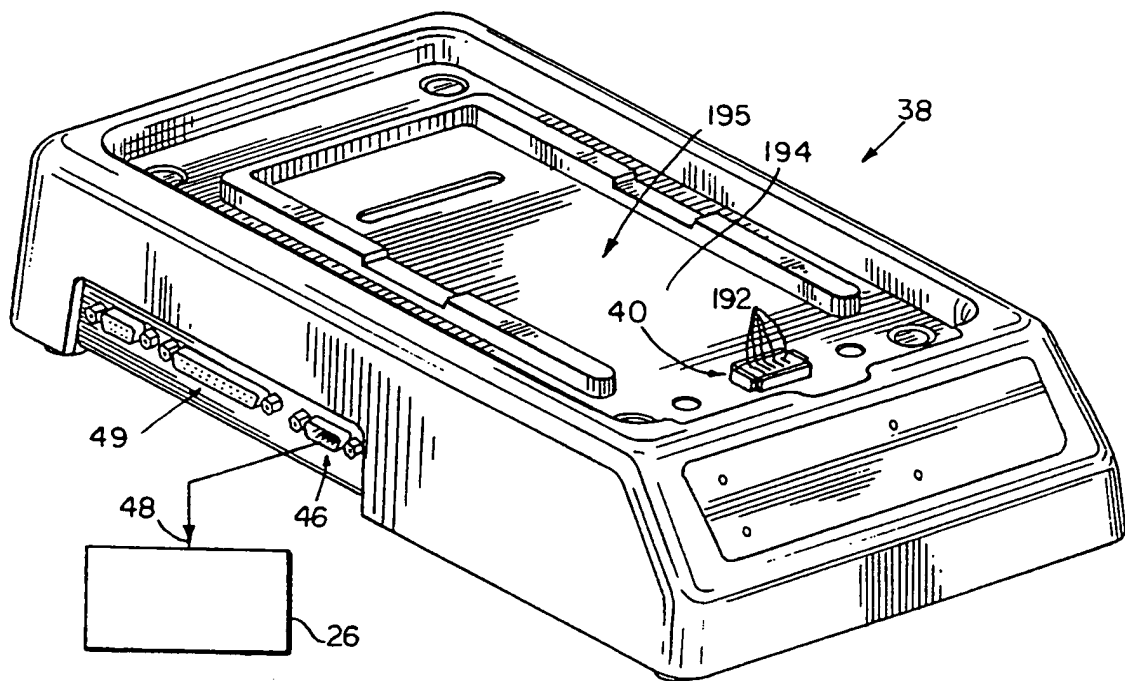
7/11



8/11

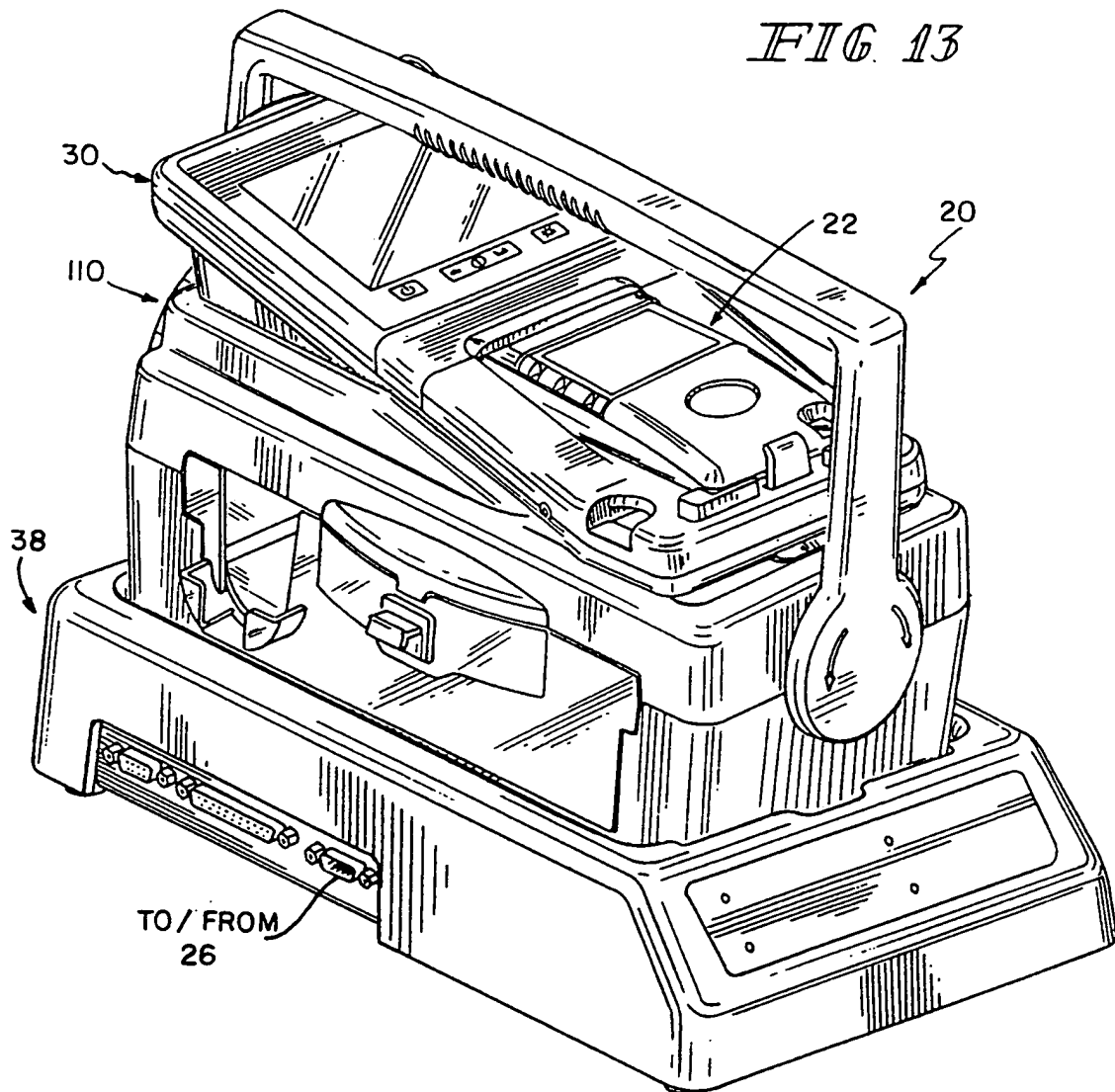


9 / 11

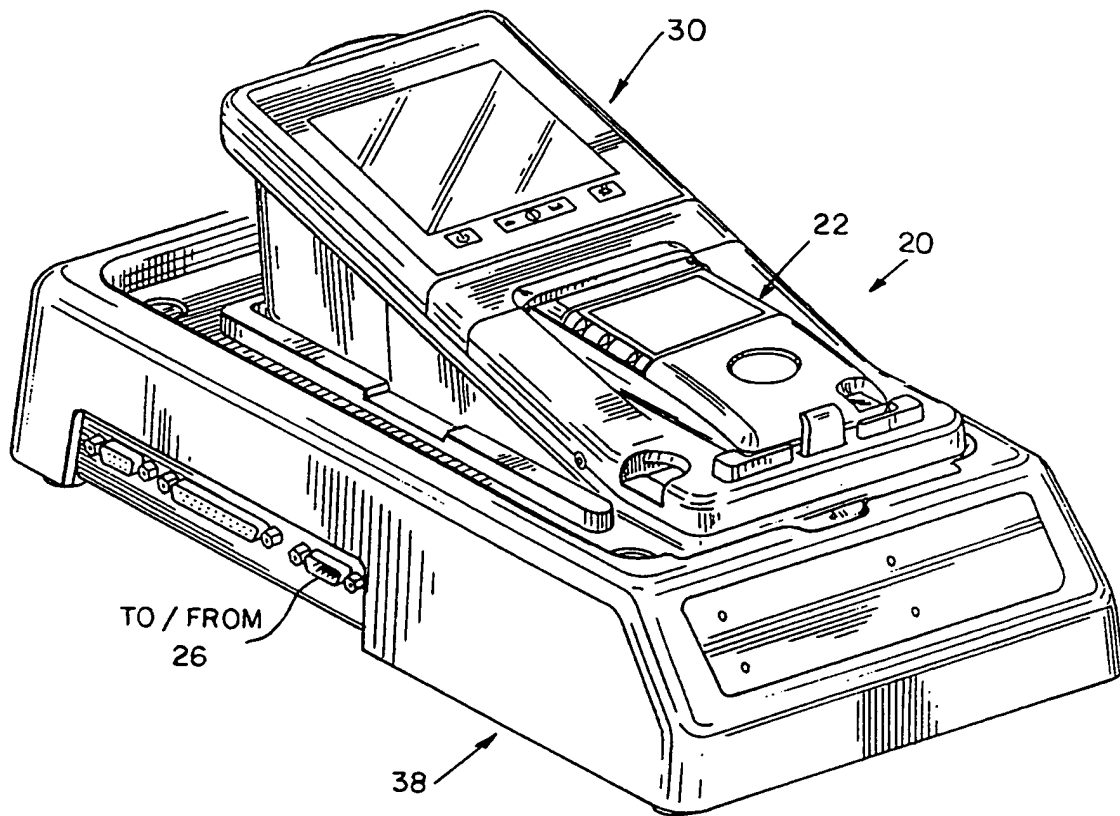
*FIG. 12*

10 / 11

*FIG. 13*



// / //



*FIG. 14*

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/05121

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 G06F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01D G06F A61B A61G A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94 24929 A (HEALTHDYNE INC) 10 November 1994 (1994-11-10) page 9, line 4 -page 10, line 33; figures 3A-3E	1-3 26
A	---	
X	US 5 371 687 A (ANDERSON JOE E ET AL) 6 December 1994 (1994-12-06) column 5, line 8-63 column 10, line 11-35; figures 1,2,7,9	1,2,4,14
Y	---	
A		3,10-13 24-26, 29,30
Y	US 5 865 745 A (SCHMITT ERIC L ET AL) 2 February 1999 (1999-02-02) abstract: figure 6	3,10-13
	---	
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

13 June 2000

Date of making of the international search report

23/06/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.  
Fax: (+31-70) 340-3018

Authorized officer

Jonsson, P.O.

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/05121

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	PATENT ABSTRACTS OF JAPAN vol. 014, no. 227 (C-0718), 15 May 1990 (1990-05-15) & JP 02 055034 A (A & D CO LTD), 23 February 1990 (1990-02-23) abstract ---	1,2,4
X	PATENT ABSTRACTS OF JAPAN vol. 014, no. 227 (C-0718), 15 May 1990 (1990-05-15) & JP 02 055033 A (A & D CO LTD), 23 February 1990 (1990-02-23) abstract ---	1,2,4
A	WO 94 13198 A (SIEMENS MEDICAL SYSTEMS INC) 23 June 1994 (1994-06-23) page 30, line 13-29 page 6, line 5 -page 7, line 4 ---	5-9,26
A	US 3 970 996 A (ITO RYUZO ET AL) 20 July 1976 (1976-07-20) abstract ---	10-13
A	US 5 572 873 A (KELLOW ROBERT C ET AL) 12 November 1996 (1996-11-12) abstract -----	24-26, 29,30

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International Application No  
**PCT/US 00/05121**

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9424929 A	10-11-1994	US 5558638 A AU 6779194 A EP 0699046 A	24-09-1996 21-11-1994 06-03-1996
US 5371687 A	06-12-1994	CA 2147484 A DE 69323094 D DE 69323094 T EP 0680645 A EP 0836135 A ES 2130397 T JP 8504045 T WO 9412950 A US 5594906 A	09-06-1994 25-02-1999 10-06-1999 08-11-1995 15-04-1998 01-07-1999 30-04-1996 09-06-1994 14-01-1997
US 5865745 A	02-02-1999	NONE	
JP 02055034 A	23-02-1990	JP 2704886 B	26-01-1998
JP 02055033 A	23-02-1990	JP 1960364 C JP 6093882 B	10-08-1995 24-11-1994
WO 9413198 A	23-06-1994	US 5375604 A AT 149083 T DE 69308322 D DE 69308322 T DK 673223 T EP 0673223 A JP 8504345 T	27-12-1994 15-03-1997 03-04-1997 17-07-1997 01-09-1997 27-09-1995 14-05-1996
US 3970996 A	20-07-1976	JP 970234 C JP 49114851 A JP 53035422 B AU 476425 B AU 6507974 A CA 1014668 A DE 2409621 A FR 2219464 A GB 1451008 A IT 1009223 B SE 405648 B	31-08-1979 01-11-1974 27-09-1978 23-09-1976 21-08-1975 26-07-1977 05-09-1974 20-09-1974 29-09-1976 10-12-1976 18-12-1978
US 5572873 A	12-11-1996	NONE	



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**